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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,656	08/08/2001	Denis Schrier	5660-D1-01-CFP	5347

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EXAMINER
REYES, HECTOR M

ART UNIT	PAPER NUMBER
1625	8

DATE MAILED: 01/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/924,656	SCHRIER ET AL.	
	Examiner	Art Unit	
	Hector M Reyes	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Paper Entry

Examiner acknowledges Applicant's:

- Request for Extension of Time filed on December 4, 2002 as Paper no. 5
- Amendment B with attach, filed on December 4, 2002 as Paper no. 6
- Terminal Disclaimer, filed on December 4, 2002.

Status of the Claims

The only claim of the instant Application under examination is Claim 1.

Rejections Withdraw

Rejection of Claim 1 under Double Patenting is withdrawn in view of Applicant's Terminal Disclaimer filed on December 4, 2002 as paper no. 7.

Rejection Modified

Rejection of Claim 1 under 35 USC 112, first paragraph is hereby modified as indicated below.

Rejection of claim 1 under 35 USC 103 is hereby modified as indicated below.

Claim Rejections - 35 USC § 101

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The claimed method it will impossible to carry out with compounds embraced by the claim but not described at all

in the disclosure. What are the starting materials and reactions conditions to prepared the same?

Claim 1 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "preventing and treating inflammatory diseases" is indefinite because it is not clear which specific inflammatory diseases are prevented and treated by following the claimed procedure. A broad interpretation as required by the Examination process would be obligated to conclude that the instant method would prevent ***any inflammatory diseases***, liberating the whole living species over the planet of such diseases. Such interpretation, although highly desirable is quite improbable in view the present state of the art.

The phrase "to a subject in need" is indefinite because there is no definition of the "subject" to be treated. Is the instant method directed to prevent and treat any

mammals? Or is only directed to treat and prevent such a diseases on humans or in any possible subject?

The phrase "anti-inflammatory amount" is unclear because it is not define is such amount is the required effective amount or a given amount which is not necessarily effective. Is any amount of the said analog enough to achieve the claimed result in any possible subject?

The phrase "GABA-analog" is clearly indefinite. As an essential characteristic of the invention, the identification and availability of the compounds to be use in the claimed method need to be disclosed. It is not clear which GABA-analogs are embraced in the claimed process. How the invention would be possible if there is no clear indication of which specific compound are required to be use according the claimed method? How analogs not disclosed in the specification but embraced in the said claim are prepared? The Examiner recommends the identification of the required analogs embraced by the claimed method as well as the proper metes and bounds of the claimed method. A patent to a claim of such a magnitude will detain whole areas of scientific development without any compensation or benefit to the public.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating the particular inflammation by using the

particular GABA analogs as indicated in the Examples given in the disclosure, does not reasonably provide enablement for:

- Treating other inflammatory diseases
- In any possible subject
- By using all possible GABA analog or
- Preventing any inflammatory disease in any subject by using any GABA analog.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Such conclusion is base upon consideration of the following factors:

The breadth of the claim

It is clear that the claim under examination is very broad. Such claim is drawn to a method for:

- Preventing and treating
- Any inflammatory disease by
- Administering to any possible subject in need
- Any anti-inflammatory amount of
- Any possible GABA analog.

The Nature of The Invention

The invention is directed to a method of prevention and treatment of a group of diseases. Elements such as the type of inflammation, the subject requiring the

treatment or prevention, the identification of the active ingredient to be used as well as the amount of such compound are all essential element of the invention. The determination of the effectiveness of the method depends on the nature of such elements. A tremendous amount of time and effort would be required in order to determine such conditions.

The Level of Predictability on the Art

In terms of the prevention of a given inflammatory disease, there is not predictability that a given compound is used in the treatment of the disease, would also be effective in the prevention of such disease. While the treatment of any disease can be shown by experimentation, prevention requires showing that via the said method, the given subject will not get the said disease in its life term. Such determination would required a lot of time and effort, specially if the said prevention:

- Is achieve in any possible subject
- With any amount of any possible GABA analog and
- Is effective against any possible type of inflammation.

Regarding the treatment of inflammation disease, it would be unpredictable that just because a given amount of a given GABA analog is effective in treating an specific subject, that any amount of any GABA analog would be effective in treating any type of inflammation in any possible subject. Determination of such possibility would clearly demand considerable time and effort because:

- There are a diverse type of inflammation
- There are important differences among the said subjects and its physical nature

- What may be effective amount in the treatment of a rat or a rabbit would highly probable be not effective against humans or elephants.

The State of the Prior art.

The word analog is directed to a series of derivatives, which have a similar structure relationship but different atoms. The synthetic preparation of such analogs not necessarily is achieve by the same synthetic approach or method. Clearly, the claimed invention does not provide enablement for the preparation of all possible GABA analogs, not even define which analogs are embraced by the said method.

Moreover, the state of the indicates that:

When compounds have "very close" structural relationship and similar utilities, without more, a prima facie case of obviousness may be made. See CAFC 1985, 769 2nd 729, 226, USPQ 277.

GABA and its salts are effective in the treatment of Inflammation JP.....

Thus, the degree of similarity is a tremendous factor in the patentability of the present invention. However,

- How similar has the GABA analog needs to be in order to be use in the claimed method and without being ruled out the prima facie obviousness case?
- How can the analysis be made if there is no indication of the possible chemical structure of the compounds?

The Existence of Working Examples

- In Example 1 of the disclosure, Applicant present the evaluation of Gabapentin in a streptococcal wall (SWC)-induced paw edema model using female Lewis rats

- In Example 2 and 3, Pregabalin was evaluated in a similar manner
- In Example 4, Gabapentin was evaluated with rats against knee joint inflammation.

There is no evaluation of any other GABA-analogs in any other subjects. Clearly, although such examples may support treatment of inflammation in such subjects and by using the said analog, there is no enablement for the use of all possible analogs in any possible subjects and using any possible amount of such analog.

Considering the above factors it is conclude that undue experimentation would be required in order to practice the invention as being described in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai, JP 60036413.

1. Scope of The Prior Art

Nagai teaches that gamma amino butyric acid and its salt are biologically active against inflammation.

2. Differences between the prior art and the claim at issue

Nagai does not teach that gamma amino butyric acid –analogs are biologically active against inflammation.

3. Level of Ordinary skill in the art

A person at a level of master degree can easily and immediately figure out the same utility for compounds that are analogs to the one which utility is already known.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness

A person of ordinary skill in the art would consider that GABA analogs are useful in the treatment of inflammation because of the close structural relationship between GABA and its analogs and the intended utility for such analogs is the same: its biological effect against inflammation. Such clear and solid case has been held as a mere *prima facie case* of obviousness, See CAFC 1985 769 F2d729, 226USPQ 870.

Response to Arguments

Applicant's arguments filed on Paper no. 6 have been fully considered but they are not persuasive.

Regarding the lack of enablement, Applicant argued that:

- The application does provide reasonable enablement for the scope as set forth in the presently pending claim because of the details of Example #3 and 4.

Applicant's attention is directed to the modified lack of enablement rejection, wherein a more detailed analysis it is clear that the said examples are not enable because there is a clear need to carry out undue experimentation in order to practice the invention as being claim. Moreover, there is a clear lack of scientific support directed to show the claimed prevention. Indeed there are compounds required in the claimed method that are not even identified, nor its preparation disclosed.

Regarding the previous rejection base upon 35 USC 103, Applicant's arguments are found moot in view of the modification of such rejection hereby included. The only argument presented that may be also extend to the present rejection is that it is not expected that the Gaba analog behave in the same manner than Gaba in terms of its biological activity against inflammation. Such argument however, does not indicate which specific analogs are being referred to and moreover lack a scientific base showing or validating the said argument.

CONCLUSION

Any inquiry concerning this communication should be directed to Hector M. Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on M to F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner 's supervisor, Allan Rotman can be reached on (703) 308-4698. The fax number for the organization where this application or proceeding is assigned is (703) 308-4556 or for regular communication and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

January 27, 2003

Hector M Reyes, PhD JD

Alan L Rotman

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